REMARKS

Claims 1-5, 7-14 and 16-24 are currently pending in the application. Claims 19-21 are withdrawn as being directed to a non-elected invention. Applicants reserve the right to present these claims in a divisional application.

Finality of the Office Action

Applicants request that the finality of the office action be withdrawn because new art has been cited against provisionally allowed claim 4. Claim 4 was rewritten in independent form, with no change in its scope.

APPLICANTS' INVENTION

Applicant's invention includes tissue implant devices which are configured to resist migration after being implanted. They comprise a flexible, helical spring made from a filament, where the filament has a rectangular cross-section. The spring includes multiple coils. Each coil possesses at least one barb that engages the surrounding tissue.

The invention also includes a method of forming such a device. The method can include the steps of forming, from a sheet of material via a photochemical etching process, a ribbon having at least one projecting barb on the edge of the ribbon, then separating the ribbon from the sheet of material, and then wrapping the ribbon into a helical coil, and forming it so that the barbs project along the edge.

CITED ART

Ahern (U.S. Pat. No. 6,620,170; "Ahern")

Ahern discloses devices and methods intended to induce fibrin growth in tissue and to promote revascularization of the tissue after implantation of the device. The device can be a frame configured to foster growth of fibrin and to permit communication between the fibrin and the surrounding tissue. The device can be associated with a fibrin promoting substance, or associated with formed fibrin. The device can also be associated with a formed thrombus or a thrombophilic substance. One of the devices is illustrated in Fig. 7, which is described (at column 6, lines 62-63) as a side view of an implant device comprising a canted coil.

Lashinski *et al.* (U.S. Pat. No. 5,868,780; "Lashinki")

Lashinski discloses a stent to hold open a tubular body structure or lumen, where the stent has at least one axial portion, preferably an axial end portion, that "stents" the tubular body structure to a lesser degree than the other axial portion of the stent. This is described at column 3, lines 43-65. At least one axial end section 12a or 12e of stent 10 (see, *e.g.*, Fig. 2) is made so that it holds open the surrounding portion of the lumen somewhat less strongly or less extensively than other portions of the stent. This is shown in Fig. 2, which shows the ends 12a and 12e slightly collapsed inwardly relative to the middle section 12c. One method of accomplishing this partial collapse is described at column 3, lines 50-54, which states that the end sections 12a and/or 12e can be made from a material having a lower modulus of elasticity or spring force than other sections.

The stated purpose of this partial collapse of the ends of the stent is to avoid abrupt transitions between the stented and unstented regions of the lumen. Abrupt transitions may trigger a body reaction at or near the site of the transition (column 1, lines 27-34), and avoiding the abruptness of such a transition area may therefore be more therapeutic.

Khosravi *et al.* (U.S. Pat. No. 6,425,915; "Khosravi")

Khosravi discloses a stent made from a roughly rectangular band which is then wound at an angle to produce a tubular structure. The band has a multiplicity of openings which form a lattice providing about 60% open space or more (Figs. 1 and 2). The width of the band is equal to at least one quarter to one-third of the maximum expanded circumference of the stent.

In one embodiment, shown in Figs. 5A and 5B, barbs are formed within the openings in the rectangular lattice, and project outwardly from the surface of the stent when the band is rolled to form the tubular coil of the stent. That is, each barb is located along the internal edge of a opening within the lattice. The barbs are not located along the edge of the rectangular band. The edges of the rectangular band are intact.

Summers (U.S. Pat. No. 5,607,445; "Summers")

Summers discloses a stent which includes a coil having a plurality of arctuate sections that alternate directions around a central axis. The stent can be made from a flat sheet of material which is photochemically etched to form a blank, and the blank is then formed into the coil.

CLAIM REJECTIONS

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 3, 7 and 24 were rejected as anticipated by Ahern, apparently on the theory that Fig. 7 of Ahern discloses a coil having a plurality of individual coils, "each having a *[sic]* edge along which is formed at least one *barb/projection edge*" which faces radially outward from the spring." (office action, section 5).

If the office action is based on the notion that the edge of the coil shown in Ahern's Fig. 7 is the barb of the present claims, such analysis is improper because it ignores the limitation that each coil has "an edge along which is formed at least one barb". The edges of the Ahern devices have no barbs. The rejection ignores the distinctions between the "edge" and the "barb" and effectively removes the "barb" limitation from the claim. The rejection should be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

The claims were rejected under 35 U.S.C. §103 as being obvious in view of Ahern and each of Lashinski, Khosravi and Summers in turn.

The office action states that "Applicant has not disclosed that having rounded barbs or barbs that face in a proximal direction away from the spring solves any stated problem or is for any particular purpose." This is not relevant to a rejection under 35 U.S.C. § 103. It is also not true.

The specification states at several points that the purpose of the barbs is to prevent migration of the device after it is implanted. See, *e.g.*, page 3, lines 9-12 and page 6, lines 16-24 ("Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the device."). Applicants have therefore asserted sufficient utility for the barbs, and respectfully submit that it is improper not to include them in examination of the claims.

The office action also states that "it appears that the *barb/projection edge* of Ahern would perform equally as well as the barbs that are rounded or face in a proximal direction" and that "the use of rounded barbs or barbs which face in a proximal direction away from the spring is deemed to be a design consideration which fails to patently distinguish over the prior art of Ahern." This is also irrelevant to an obviousness rejection.

A stated in the specification, the inclusion of one or more barbs on the claimed devices is for the purpose of preventing the migration of the device out of tissue after implantation. The barbs are functional and do not present a "design consideration." Design choices are discussed in the Manual of Patent Examining Procedure (MPEP) § 2144.04(VI)(C):

> *C. Rearrangement of Parts*
> *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

The stated utility of the barbs is that they prevent the migration of the device. They are included to prevent migration of the device, not for decoration.

The requirements for supporting a rejection based on lack of utility is discussed in the MPEP § 2107(II)(C):

> Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner

> should specifically explain the scientific basis for his or her factual conclusions.

Applicants' specification provides an asserted a utility for the barbs that is specific and substantial. The office action provides no explanation, evidence, or reasoning why the asserted utility is not credible. The barbs must therefore be considered to be part of the claimed devices. It is improper to discount stated features of the claims in order to apply a rejection based on art lacking the claimed features.

The Ahern devices possess no such barbs, and the reference therefore cannot render obvious applicants' claimed devices. The rejections on the basis of this reference should be reconsidered and withdrawn.

Claims 8-11 and 22 were also rejected as obvious in view of the combination of Ahern and Lashinski. The Lashinski reference discloses a stent having different regions with differing moduli of elasticity.

However, none of the Lashinski devices possess barbs. Where neither reference discloses devices having barbs, their combination cannot render obvious devices having barbs. The rejection on this basis should be reconsidered and withdrawn.

The office action also rejected claims 12-13 as obvious in view of Ahern and Khosravi. Khosravi discloses a stent formed of a roughly rectangular band, rolled at an angle to form a tubular stent. Khosravi does not disclose a helical spring implant with at least one barb along the edge of a coil. Rather, the rectangular band of Khosravi possesses openings across it which form a lattice (see, *e.g.*, Figs. 1-2), and within the interior of these openings a barb can be formed (see, *e.g.*, Fig. 5). When the rectangular band is rolled to form the tube, the barbs project outwardly on the surface of the tubular stent.

The barbs of the Khosravi stent are formed in the interior of the rectangular band, not along the edge, as is required by claim 1. Claims 12 and 13 depend from claim 1, and include the requirement that the barbs be located along the edge of the coils. As stated above, Ahern discloses no barbs at all. The combination of these two claims cannot render obvious applicants'

claims, and it is respectfully requested that the rejection on this basis be reconsidered and withdrawn.

Claims 14 and 16-18 were also rejected in view of Ahern combined with Summers. Summers discloses a stent which includes a coil having a plurality of arctuate sections that alternate directions around a central axis. The stent can be made from a flat sheet of material which is photochemically etched to form a blank, and the blank is then formed into the coil.

The devices disclosed in Summers possess no barbs, as is required by the claims. The Ahern devices also possess no barbs. Because neither reference discloses devices having barbs, their combination cannot render obvious devices having barbs. Applicants therefore respectfully request that the rejection on this basis be reconsidered and withdrawn.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

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